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| In re Application of: | Robert E. Burgmeier, Richard Goodin, Joseph Delaney Jr. |
| Application No.: | 10/822581 |
| Filed: | April 12, 2004 |
| For: | Adhesion Technique for Incompatible Polymers Using Modified Polymer Tie Layers |
| Examiner: | Thao T. Tran |
| Group Art Unit: | 1711 |
| Firm Docket No.: | S63.2B-10865-US01 |

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Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS

Date: November 16, 2006

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Docket No.: S63.2-10865-US01

AMENDED BRIEF ON APPEAL

This is a Brief on Appeal for the above-identified application in which Claims 1-8, 10-13 and 39-44 were finally rejected in an Office Action mailed **December 27, 2005**. A Notice of Appeal was filed in this case on May 17, 2006. An Appeal Brief in accordance with 37 C.F.R. § 41.37 was filed on 17 July 2006. A Notice of Non-compliant Appeal Brief was mailed on October 18, 2006. This amended brief is submitted under protest that the Notice of Non-compliant Appeal Brief constituted an unauthorized and improper editorial interference with applicant's presentation of its case on appeal, was interposed for delay, and is arbitrary, capricious and volatile of due process.

Any applicable fees and any required petition for extension of time for filing this amended brief therefor are dealt with in the accompanying Transmittal Letter.

(i) **Real Party in Interest**

The application is assigned to Scimed Life Systems, Inc., (which has since changed its name to Boston Scientific Scimed, Inc.), SciMed Life Systems, Inc., One SciMed Place, Maple Grove, MN 55311-1566, a Minnesota Corporation. The assignee is a subsidiary of

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Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts, 01760-1537,
a Delaware Corporation.

(ii) Related Appeals and Interferences

No related appeals or interferences are pending.

(iii) Status of claims

Claims 1-8, 10-13 and 39-44 are pending and have been rejected. No claims have been allowed, withdrawn, objected to or cancelled. The claims that are being appealed are 1-8, 10-13 and 39-44.

(iv) Status of amendments ¹

An amendment after final was filed January 31, 2006. A first Advisory Action was mailed February 14, 2006. The first Advisory Action acknowledged that "the proposed amendments overcome the 102 rejection over Wang '969 or Samuelson '683," but the January 31 amendment was refused entry.

On March 22, 2006, applicant also filed a Supplemental Response to the rejection on March 22, 2006 resubmitting the claim amendments previously refused entry and requesting withdrawal of the finality of the December 27, 2006 Office Action. In a second Advisory Action mailed April 14, 2006, the applicant was informed that, upon filing a Notice of Appeal the amended claims as filed March 22, 2006 would be entered, but that the Final status remained and "[t]he rejections of the claims are as set forth in the Final rejection."

A Notice of Appeal filed on May 17, 2006. In view of the second Advisory Action's statement, the claims stand in the form submitted in the March 22, 2006 Supplemental Response.

¹ Substantive content has been deleted under protest. Statement of the reason for submission of two post-final amendments considered pertinent to reporting the status of the post-final amendments. 37 CFR §41.37(c)(1)(iv).

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(v) Summary of claimed subject matter²

The rejected claims pertain to laminate articles having a two layers of first and second polymer materials, respectively, and a tie-layer in-between the first and second polymer material layers. The tie layer is obtained by melt modifying one of the two polymer materials using a coupling agent that is reactive with functional groups on the other of the two polymer materials.

According to independent claim 1, the invention is an article comprising a laminate having first and second layers and a tie-layer therebetween bonding the first and second layers, the first and second layers formed, respectively, of first and second polymer materials, the first and second polymer materials being different [pg 2, lines 5-15], wherein

the first and second polymer materials, respectively, have first and second functional groups thereon [pg 11, lines 7-8], and

the tie layer is formed of a tie-layer polymer material obtained by melt modification of one of the first or the second polymer materials [pg 2, lines 6-7], said melt modification comprising incorporation therein of at least 5% by weight of a coupling agent [pg 3, lines 17-18], the coupling agent having functional groups thereon, at least some of which are reactive in the melt with at least the functional groups on the other of said first and second polymer materials [pg 2, lines 13-14], said coupling agent being selected from the group consisting of polyepoxides, polyoxazalines, polycarbodiimides, and polyisocyanates [pg 5, ln 14 - pg 6, ln 8].

According to independent claim 12, the invention is an article comprising a laminate having first and second layers and a tie-layer therebetween bonding the first and second layers, the first and second layers formed, respectively, of first and second polymer materials, the first and second polymer materials being different [pg 2, lines 5-15], wherein

the first and second polymer materials, respectively, have first and second functional groups thereon [pg 11, lines 7-8], and

the tie layer is formed of a tie-layer polymer material obtained by melt modification of one of the first or the second polymer materials [pg 2, lines 6-7], said melt

² Substantive content has been deleted under protest. A sentence stating the disclosed utility is considered important to explaining the subject matter of the independent claims. 37 CFR §41.37(c)(1)(v).

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modification comprising incorporation therein of at least 5% by weight of a coupling agent [pg 3, lines 17-18], the coupling agent having functional groups thereon, at least some of which are reactive in the melt with at least the functional groups on the other of said first and second polymer materials [pg 2, lines 13-14], the tie layer material further comprising a catalyst for reaction of the coupling agent with functional groups on said other of said first and second polymer materials [pg 2, lines 16-19; pg 6, line 17 - pg 7, line 27].

(vi) Grounds of Rejection to be Reviewed on Appeal

Review on appeal is requested of the Examiner's contention that Claim 44 is indefinite (Argument 1, below).

Review on appeal is also requested of the Examiner's contention that Claims 1-12, 39-40 and 43 are anticipated by US 6,355,358, Boer et al (Arguments 2 & 3, below).

Review on appeal is also requested of the Examiner's contention that claims 1-13 are obvious from Wang et al, US 5,195,969, or Samuelson et al, US 6,464,683, either one taken with Shimura et al, US 5,441,488 (Arguments 4 & 5, below).

Review on appeal is also requested of the Examiner's contention that claims 12-13, and 41-42 are obvious from Boer et al taken with Shimura et al (Argument 6, below).

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(vii) Argument

1. The Examiner Erred in rejecting claim 44 Under 35 USC 112 as indefinite.

Claim 44 was rejected as indefinite for reciting a method rather than a laminate. The second Advisory Action states: "[t]he rejections of the claims are as set forth in the Final rejection." Accordingly it is understood that this rejection is being maintained.

Claim 44 has been amended to recite "a laminate." This amendment has now been entered. Amended claim 44 is now properly dependent on the antecedent claim 41. No indefiniteness arises from the current form of the claim. The rejection of claim 44 under 35 USC §112 should therefore be reversed.

2. The Examiner Erred in rejecting claims 1-8, and 10-11 as anticipated by Boer et al., US 6,355,358.

Claim 1 as currently amended recites that the coupling agent is selected from the group consisting of polyepoxides, polyoxazalines, polycarbodiimides, and polyisocyanates.

Anticipation under 35 U.S.C. Section 102(e) requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); *In re Robertson*, 49 USPQ2d 1949 (Fed. Cir. 1999); *In re Lowry*, 32 USPQ2d 1031 (Fed. Cir. 1994); *Continental Can Co. USA Inc. v. Monsanto Co.*, 20 USPQ2d 1746 (Fed. Cir. 1991); *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 7 USPQ2d 1315 (Fed. Cir. 1988); *In re Marshall*, 578 F.2d 301, 198 USPQ 344 (CCPA 1978); *In re Arkley*, 455 F.2d 586, 172 USPQ 524 (CCPA 1972).

Boer et al pertains to laminates which use an adhesion promoter layer between two polymer layers. However the Boer et al adhesion promoter layer is not formed using any of the coupling agents identified in claim 1. The adhesion promoters of Boer et al comprise a graft copolymer prepared using the following monomers:

- a) from 0.5 to 25% by weight, based on the graft copolymer, of a polyamine having at least 4 nitrogen atoms and having a number average molecular weight M_n of at least 146 g/mol
- b) polyamide-forming monomers selected from lactams, ω -aminocarboxylic acids

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and/or equimolar combinations of diamine and dicarboxylic acid. [Col. 2, line 55 - col. 3, line 6.]

These components are not polyepoxides, polyoxazalines, polycarbodiimides, or polyisocyanates, nor are the graft copolymers prepared therefrom.

Boer et al also mentions as other optional ingredients of the adhesion promoter composition:

- II. from 10 to 85 parts by weight of a polyamide;
- III. from 10 to 85 parts by weight of a polyester; where the sum of the parts by weight of I, II and III is 100; and
- IV. a maximum of 40 parts by weight of additives selected from impact-modifying rubber and/or conventional auxiliaries or added materials. [Col. 8, lines 7-25.]

As to items II and III, these also are not polyepoxides, polyoxazalines, polycarbodiimides, or polyisocyanates. As to item IV, as examples of impact-modifying rubbers, Boer identifies:

[E]thylene-propylene or ethylene-propylene-diene copolymers (EPA-0 295 076), polypentenylene, polyoctenylene, random or block copolymers of alkenyl-aromatic compounds with aliphatic olefins or dienes (EP-A-0261 748) or core/shell rubbers having a tough, elastic core of (meth)acrylate, butadiene or styrenebutadiene rubber having glass transition temperatures (T_g) of $<-10^\circ\text{C}$, where the core may be crosslinked and the shell may be built up from styrene and/or methyl methacrylate and/or further unsaturated monomers (DE-A 21 44 528 and 37 28 685). [Col. 8, lines 48-53; Col. 6, lines 46-54; col. 7, lines 36-40.]

These also are not polyepoxides, polyoxazalines, polycarbodiimides, or polyisocyanates.

Finally, as to conventional auxiliaries or added materials Boer identifies:

flame retardants, stabilizers, plasticizers, processing auxiliaries, fillers, in particular fillers which improve the electrical conductivity, reinforcing fibers, pigments or the like. [Col. 6, lines 55-62; col. 7, lines 40-47]

Once again, there is no teaching of polyepoxides, polyoxazalines, polycarbodiimides, or polyisocyanates.

The Examiner has pointed to *nothing* in the Boer et al reference that can be identified as a teaching to employ a polyepoxide, polyoxazaline, polycarbodiimide, or polyisocyanate in the adhesion promoter layer. No such teaching can be found. The rejection of claim 1, and of claims 2-8, and 10-12 which depend therefrom, should therefore be reversed.

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3. The Examiner Erred in rejecting claims 12, 39-40 and 43 as anticipated by Boer et al, US 6,355,358.

The applicable standard for determination of anticipation is stated in argument 2, above.

Claim 12 is independent. Claims 39-40 and 43 depend from independent claim 41. Both claims 12 and 41 recite that the tie layer material further comprises a catalyst for reaction of the coupling agent with functional groups on said other of said first and second polymer materials.

Boer et al has been described above. The Examiner has pointed to nothing in the Boer et al reference that can be identified as a teaching to employ a catalyst for reaction of the coupling agent with functional groups on said other of said first and second polymer materials in the Boer et al adhesion promoter composition. Notable further is the fact that claim 41, from which claims 39-40 and 43 all depend, has not been rejected for anticipation by Boer et al.

At least for the reason that Boer et al does not teach a tie-layer comprising a catalyst, the rejection of claims 12, 39-40 and 43 for anticipation by Boer et al. should be reversed.

4. The Examiner Erred in rejecting claims 1-8, and 9-11 as obvious from Wang et al, US 5,195,969, or Samuelson et al, US 6,464,683, either one taken with Shimura et al, US 5,441,488.

To support an obviousness rejection, the cited prior art must specifically suggest the combination as claimed, and it must be applied in the context of their significance to a technician at the time the invention was made, without knowledge of the solution. It is impermissible, simply to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template, picking and choosing among isolated disclosures in the various documents to supply elements to fill the gaps. The cited documents must provide some teaching, suggestion or motivation whereby the applicant's combination would have been obvious; again at the time the invention was made. U.S. patent law is replete with cases that illustrate this principle. See e.g. *In re Kotzab* 55 USPQ2d 1313 (Fed. Cir. 2000); *Winner*

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International Royalty Corp. v. Wang, 53 USPQ2d 1580, 1586 (Fed Cir 2000); *In re Dembiczak*, 50 USPQ2d 1614, 1616-17 (Fed. Cir. 1999); *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988); *In re Gorman*, 18 USPQ2d 1885, 1888 (Fed Cir. 1991); *In re Oetiker*, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992); and *In re Fritch*, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992).

The Examiner's rationale for this rejection is as follows:

Wang teaches a laminate in a medical balloon or a catheter, the laminate comprising an innermost layer of polyethylene, an outermost layer of Nylon (polyamide), and a layer of Plexar sandwiched in between. Plexar is an anhydride-modified polyolefin. (See Figs 3-4; col. 4, in. 14-15, 46-49).

Samuelson teaches a laminate in a medical tubing, the laminate comprising an outer layer 16, a core layer 12, and an intermediate tie layer 14 interposed between the outer layer and the core layer (see abstract; Fig. 1). The outer layer comprises a polyester or polyamide; the core layer comprises a polyethylene; and the intermediate tie layer comprises a polymeric material comprising functionality capable of adhering outer layer 16 to core layer 12. (See col. 6, in. 5-6, 41-45, 57-59). The polymer of the intermediate tie layer comprises modified olefinic polymer having an anhydric moiety or maleic acid (see col. 7, in. 12-51).

However, neither Wang nor Samuelson teaches the amount of the modifying compound of the polyolefin in the intermediate layer.

Shimura teaches a modified polyolefin as an adhesive in a laminate, the modified polyolefin comprising maleic anhydride is deposited on polyolefin or polyamide (see col. 4, in. 51-56; col. 5, in. 1-7). The content of acid anhydride is 0.5-50% (see col. 5, in. 9-10). The composition further comprises a catalyst, such as tertiary amine, to promote the reaction of the acid anhydride (see col. 5, in. 40-43).

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have employed the modified polyolefin with the acid anhydride content and the catalyst, as taught by Shimura, in the tie layer of Wang or Samuelson, for the purpose of enhancing adhesion between the tie layer and the outer and inner layer. This is because Shimura teaches that the use of such modified polyolefin and catalyst would have improved bonding and crosslinking between the modified polyolefin and polyamide or polyester.

Claim 1 recites the coupling agent is selected from the group consisting of polyepoxides, polyoxazalines, polycarbodiimides, and polyisocyanates. The Examiner does not assert that Plexar® polymers of Wang are modified with any of these coupling agents. The Examiner further does not assert that Samuelson et al or Shimura et al would lead a skilled person to use of such a coupling agent component. Instead the Examiner's comments only go to use of anhydride modified polymers as tie-layers. Therefore the combination, even if proper,

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does not meet the recitations of claim 1 and so cannot render obvious the invention of claim 1 or claims 2-8 and 11 which depend therefrom.

5. **The Examiner Erred in rejecting claims 12 and 13 as obvious from Wang, US 5,195,969, or Samuelson, US 6,464,683, either one taken with Shimura et al, US 5,441,488.**

The applicable standard for determining obviousness, as well as the Examiner's rationale for the rejection, are set forth in argument 4 above.

Claim 12 recites the use of a catalyst in the tie layer. As we have seen above the Final Action asserts that it would have been obvious to employ a catalyst as taught by Shimura et al in the tie layer of Wang or Samuelson. The Examiner has clearly misunderstood Shimura et al.

Shimura et al describes a water swellable polymer layer bound to a "matric" material that may contain an acid polymer or acid anhydride polymer or which is coated with such an acid or anhydride polymer. Shimura et al mentions that a tertiary amine catalyst may be used to promote reaction of the water-swellable polymer with the acid anhydride on the surface of the matric material. The portion of the disclosure cited by the Examiner (Col. 5, lines 40-43) does not state the location of the catalyst. The document when taken as a whole, however, clearly demonstrates that this teaching is directed to the use of a catalyst in the water swellable polymer layer, *i.e. the outer layer*, not in the acid-anhydride containing polymer. See *e.g.* Examples 12-14, 16 and 17 (1% by weight pyridine solution) and Example 18 (1% by weight of triethyl amine solution). Nowhere in this reference is there a teaching or suggestion to employ such a catalyst in the matric material or in an acid or anhydride polymer layer.

Furthermore, in Shimura et al, the outer layer containing the catalyst is deposited from a solution, not a melt as recited in the rejected claims, so the conditions of use are not analogous to the conditions of preparation of the claimed tie-layer. Thus, if properly combinable, Shimura et al might arguably lead one to incorporate the catalyst into a first or second polymer layer applied from solution. However, there is no teaching or suggestion to include a catalyst in a tie layer, much less a tie layer obtained from a melt. Consequently, the assertion that the skilled person would have been led by this reference to employ a catalyst in the

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tie layer of Wang et al or Samuelson et al can only have been conceived with improper hindsight reconstruction of the Shimura et al reference.

At least for the reason that Shimura et al does not teach or suggest using a catalyst in a tie layer or a layer analogous thereto, the inventions of claim 12, and of claim 13 which depends therefrom, are not rendered obvious by the combination of Shimura et al with either Wang et al or Samuelson et al.

6. The Examiner Erred in rejecting 12-13, and 41-42 as obvious from Boer et al taken with Shimura et al, US 5,441,488.

The applicable standard for determining obviousness of a claimed invention is set forth in argument 4 above.

The rejected claims all recite a catalyst in the tie layer.

As previously noted the Examiner has pointed to nothing in the Boer et al reference that can be identified as a teaching to employ in Boer et al's adhesion promoter composition, a catalyst for reaction of the coupling agent with functional groups on said other of said first and second polymer materials.

Shimura et al's catalyst is put into an *outer* layer produced by applying a solvent solution of catalyst and outer layer polymer onto an acid-anhydride polymer substrate or coating. See Examples 12-14, 16 and 17 (1% by weight pyridine solution) and Example 18 (1% by weight of triethyl amine solution). There is no teaching or suggestion to incorporate the catalyst into the acid-anhydride polymer substrate or layer. Therefore, if properly combinable, Shimura et al might arguably have lead one to incorporate a catalyst into Boer et al's layer I or layer II, but there is no teaching that would have led to its use in the adhesion promoter material therebetween. At least for the reason that neither Boer et al nor Shimura et al teach or suggest using a catalyst in a tie layer or a layer analogous thereto, the inventions of claims 12-13 and 41-42 are not rendered obvious by the combination of Shimura et al with Boer et al.

7. Conclusion

The informality in claim 44 has been corrected by the Amendment filed March 22, 2006 and the Examiner has not articulated a sound ground for continuing to assert the §112

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indefiniteness rejection of claim 44. The Examiner's contentions: that claims 1-12, 39-40 and 43 are anticipated by US 6,355,358, Boer et al; that claims 1-13 are as obvious from Wang et al, US 5,195,969, or Samuelson et al, US 6,464,683, either one taken with Shimura et al, US 5,441,488; and that claims 12-13, and 41-42 are obvious from Boer et al taken with Shimura et al, have all been demonstrated to be flawed and untenable under the well-established principles applicable to anticipation and obviousness rejections. The Board is therefore respectfully requested to reverse the rejections with instruction to pass the application to issue.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: November 16, 2006

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(viii) **Claims Appendix**³

1. An article comprising a laminate having first and second layers and a tie-layer therebetween bonding the first and second layers, the first and second layers formed, respectively, of first and second polymer materials, the first and second polymer materials being different, wherein

the first and second polymer materials, respectively, have first and second functional groups thereon,

the tie layer is formed of a tie-layer polymer material obtained by melt modification of one of the first or the second polymer materials, said melt modification comprising incorporation therein of at least 5% by weight of a coupling agent, the coupling agent having functional groups thereon, at least some of which are reactive in the melt with at least the functional groups on the other of said first and second polymer materials, said coupling agent being selected from the group consisting of polyepoxides, polyoxazalines, polycarbodiimides, and polyisocyanates.

2. An article as in claim 1 wherein the coupling agent functional groups further comprise functional groups which are reactive in the melt with the functional groups of said one of the first and second polymer materials.

3. An article as in claim 1 wherein the tie layer polymer has been irradiatively crosslinked.

4. An article as in claim 1 wherein the first polymer material is a polyester.

5. An article as in claim 4 where the second polymer material is a polyolefin or a polyamide.

³ Non-substantive deleted under protest. Claim identifiers are not prohibited in 37 CFR 41.37(c)(1)(vii).

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6. An article as in claim 5 wherein the tie layer polymer material is a modified polyolefin or polyamide.
7. An article as in claim 1 wherein the first polymer material is a polyester or a polyamide, the second polymer material is a polyolefin and the tie layer material is obtained by modifying the second polymer material.
8. An article as in claim 7 wherein at least a portion of the second polymer material and the tie-layer polymer material have been crosslinked after formation of the laminate.
10. An article as in claim 9 wherein the coupling agent is present in the tie layer material in an amount of from about 7% to about 35% by weight.
11. An article as in claim 1 wherein the coupling agent is incorporated into the tie layer material in an amount of 10-20% by weight.
12. An article comprising a laminate having first and second layers and a tie-layer therebetween bonding the first and second layers, the first and second layers formed, respectively, of first and second polymer materials, the first and second polymer materials being different, wherein
 - the first and second polymer materials, respectively, have first and second functional groups thereon,
 - the tie layer is formed of a tie-layer polymer material obtained by melt modification of one of the first or the second polymer materials, said melt modification comprising incorporation therein of at least 5% by weight of a coupling agent, the coupling agent having functional groups thereon, at least some of which are reactive in the melt with at least the functional groups on the other of said first and second polymer materials, the tie layer material further comprising a catalyst

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for reaction of the coupling agent with functional groups on said other of said first and second polymer materials.

13. An article as in claim 12 wherein the catalyst is selected from the group consisting of tri-valent phosphorous compounds, pentavalent phosphoric compounds, tin compounds, titanate compounds, tertiary amines, blocked amines, and mixtures thereof.

39. A laminate as in claim 41 wherein the coupling agent is present in the tie layer material in an amount of from about 7% to about 35% by weight.

40. A laminate as in claim 41 wherein the coupling agent is incorporated into the tie layer material in an amount of 10-20% by weight.

41. A laminate which comprises first and second layers of different polymers, with an adjoining tie layer between the first and second layers, wherein the tie layer is a melt modified product of one of the two different polymers and a coupling agent that is reactive with at least the other of the two different polymers the tie layer material further comprising a catalyst for reaction of the coupling agent with functional groups on said other of said first and second polymer materials.

42. A laminate as in claim 41 wherein the catalyst is selected from the group consisting of tri-valent phosphorous compounds, pentavalent phosphoric compounds, tin compounds, titanate compounds, tertiary amines, blocked amines, and mixtures thereof.

43. A laminate as in claim 41 wherein the coupling agent is incorporated into the tie layer material in an amount of about 0.5% or more.

44. A laminate as in claim 43 wherein the coupling agent is a member of the group consisting of anhydrides of polycarboxylic acids, polyepoxides, polyoxazalines, polycarbodiimides, and polyisocyanates.

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(ix) Evidence appendix.

Not applicable

(x) Related proceedings appendix.

Not applicable

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